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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,657	03/28/2001	Rhonda C. Brandon	CL001006-CIP	2506

7590 07/27/2004

CELERA GENOMICS CORPORATION
45 West Gude Drive C2-4#20
Rockville, MD 20850

EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,657	BRANDON ET AL.	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *seq. comparison*.

DETAILED ACTION

Response to Amendment

1. Amendment filed 6 May 2004 has been entered. Claims 4, 8-9 and 24-29 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 6 May 2004, have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 101

4. Claims 4, 8-9, and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The reason for the rejection was wet forth in the previous office action. Applicants argue that SEQ ID NO:2 is a novel gamma-aminobutyic acid A (GABA-A) receptor and thus has utility as supported by page 13-14 of the specification. However, the specification does not disclose any binding or physiological results from experiments. Furthermore, the closest prior art of record, Walke et al. (WO 02/00720) discloses the protein with 100% identity but does not disclose any binding or physiological results from experiments. Thus, the claimed nucleic acid encoding SEQ

ID NO:2 is drawn to an orphan receptor whose ligand is not known. The naming of the receptor is based on sequence identity to gamma-aminobutyic acid A receptor, but the sequence identity of the claimed SEQ ID NO:2 and previously identified GABA-A receptor known in the art is about 40% which is quite low. Furthermore, GABA receptors are composed of 5 subunits which are quite divergent forming an ion channel which is activated by ligands. The GABA ligand provides the nexus to the diseases because the drugs ligand agonists or antagonists which can be administered for treatment of diseases. However, since the claimed receptor is an orphan, the ligand is not known for the receptor nor its function thus lacking utility. The orphan receptors lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966)* stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search, but compensation for its successful conclusion." Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics.

Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors and host cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

5. Claims 4, 8-9, and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

6. Claims 4, 8-9, and 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Walke et al.(WO 02/00720).

Walke et al. discloses nucleic acid encoding SEQ ID NO:2 which is 100% identical to claimed SEQ ID NO:2 (see attachment). Walke et al. discloses the vector comprising the sequence and the method of producing the protein recombinantly (pages 22-26).

Applicants request proof showing that the WO 02/00720 entitles the priority date of June 27,2000. The WO 02/00720 on the first title page on the first column, item #30 recite the priority of the PCT publication.

Applicants argue that present application entitles the priority date of 12/6/2000. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 4, 8-9, and 24-29 of this application for the reasons provided above. See MPEP 706.02.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20020082407A1 is a cumulative reference with Walke et al. because it is the corresponding US patent.

WO 02/22684 is a cumulative reference with Walke et al. because the reference also discloses nucleic acid encoding SEQ ID NO:2 which is 100% identical to claimed SEQ ID NO:2.

8. No claims are allowed. Claims 25-26 are free of prior art. Examiner inadvertently indicated that claims 24-25 were free of prior art when it should have been claims 25-26 as indicated now.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
21 July 2004